

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

IN RE DIGITEK® PRODUCTS
LIABILITY LITIGATION

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

**PRETRIAL ORDER #16
(Case Management and Scheduling Order)**

This Order shall govern all cases (1) transferred to this Court by the Judicial Panel on Multidistrict Litigation; (2) any tag-along actions subsequently transferred to this Court by the Judicial Panel on Multidistrict Litigation; and (3) all related cases originally filed in this Court or transferred or removed to this Court. This Order applies to all Plaintiffs in federal actions and to Defendants Actavis Totowa LLC, and Actavis Inc. and Actavis Elizabeth, LLC (“Defendants Actavis”)¹ and Defendants Mylan Pharmaceuticals, Inc., UDL Laboratories, Inc., Mylan Inc., and Mylan Bertek Pharmaceuticals, Inc. (“Defendants Mylan”)² in the federal action in which each such Defendant was properly served.

All subsequent Orders of this Court with the designation “All Actions” entered in MDL-1968 shall likewise apply to all cases that are, or become, part of this MDL, regardless of whether that case was part of MDL-1968 when the Order was entered.

¹ Defendants Actavis maintain that Actavis Elizabeth LLC is not a proper party and therefore do not waive any argument regarding its inclusion in this litigation.

² Defendants Mylan maintain that Mylan Inc. and Mylan Bertek Pharmaceuticals, Inc. are not proper parties and therefore do not waive any argument regarding their inclusion in this litigation.

I. PLEADING ISSUES

A) Master Complaint. The Master Complaint that has been filed shall not constitute the inception of a new “case or controversy” in this district and shall not supersede or render moot the pending separate actions that were transferred to this district for pretrial proceedings by the Judicial Panel for Multidistrict Litigation. The filing and service of the Master Complaint does not toll any applicable statutes of limitations as to any individual Plaintiff, and does not relieve any individual Plaintiff of the requirement to perfect service of process of his or her Short Form Complaint. The counts of the Master Complaint are not deemed automatically included in any particular case.

B) Master Answer and Rule 12 Motion. Within forty-five (45) days after the entry of this Order, each Defendant named in the Master Complaint shall file a Master Answer or a Fed. R. Civ. P. 12 motion in response to the Master Complaint. A Defendant’s filing of a Master Answer does not preclude the filing of Fed. R. Civ. P. 12 motions or any other motion in any particular case at other times, as appropriate. Responses will be due no later than 30 days after the filing of any Rule 12 motion, and replies no later than 14 days thereafter.

C) Short-Form Complaints. All cases filed in this MDL after the date of the filing of the Master Complaint shall be filed via a Short-Form Complaint. Any case filed in any U.S. Federal Court may be filed via a Short Form Complaint. The Short-Form Complaint shall indicate those counts from the Master Complaint that are being asserted in the individual case. Plaintiffs will not be required to file a Short-Form Complaint in cases transferred to the MDL from state courts in which a complaint and answer were already filed.

D) Answers to Short-Form Complaints Not Required. Defendants are not required to file answers to Short-Form Complaints. An entry of appearance shall constitute a denial of all allegations in the Short-Form Complaint and an assertion of all defenses that are included in the

Defendant's Master Answer. This paragraph does not preclude the filing of Rule 12 motions or any other motion in any particular case at other times, as appropriate.

II. SERVICE OF PROCESS

To eliminate disputes over service of process and to reduce the expense of service of process, Defendants Actavis and Defendants Mylan agree to waive service of process in this action under Fed. R. Civ. P. Rule 4, and agree to accept service of the Summons and Complaint in the above-referenced matter by registered mail, return receipt requested, upon the following:

For Defendants Actavis:

Richard A. Dean, Esq.
Tucker Ellis and West LLP
1150 Huntington Building
925 Euclid Avenue
Cleveland, Ohio 44115

For Defendants Mylan:

Harvey L. Kaplan, Esq.
Shook Hardy and Bacon LLP
2555 Grand Boulevard
Kansas City, Missouri 64108

Service will be effective only if addressed as above, or if perfected in accordance with the service provisions of the Federal Rules of Civil Procedure. For service under this section, a copy of each notice of Service of the Summons and Complaint shall be provided to Defendants' Liaison Counsel and Plaintiffs' Liaison Counsel.

The Court orders that service effected in accordance with this section shall be deemed good and sufficient service on Defendants Actavis and Defendants Mylan (collectively "Defendants"). By agreeing to this waiver of service, Defendants Actavis and Defendants Mylan do not waive any claims, affirmative defenses or other defenses of any nature whatsoever except for those relating to service of process. If service is perfected under the Federal Rules of Civil Procedure, Defendants Actavis and Defendants Mylan do not waive any claims, affirmative defenses or other defenses of any nature whatsoever, including those related to service of process. Service of process will be perfected ten (10) days after service via registered mail. This procedure shall apply to Digitek® product liability cases filed in or

removed to federal court only, unless service is otherwise perfected under the Federal Rules of Civil Procedure, and not to any other litigation.

Defendants' responsive pleadings, including Rule 12 motions, filed under this section shall be due forty-five (45) days after service.

III. PLEADINGS AND MOTIONS

A) Pleadings. Deadlines for answers or responses to the Complaints in all individual actions are hereby suspended, except as otherwise set forth herein.

B) Class Certification.

1) Plaintiffs' deadline to request class certification of any wrongful death, personal injury or medical monitoring putative class is one hundred eighty (180) days from the date of this Order. Plaintiffs' motion and brief in support shall be filed and served within one hundred ninety (190) days from the date of this Order. Plaintiffs' deadline to request class certification of any other putative classes is one hundred and ninety-four (194) days from the date of this Order. Plaintiffs' motion and brief in support shall be filed and served within two hundred and four (204) days from the date of this Order.

2) Discovery on class issues shall be subject to the time limitations set out in Section VII(G) below.

3) Defendants' response brief(s) to Plaintiffs' motion(s) for class certification shall be filed and served thirty (30) days after the filing of each respective class certification motion(s) and accompanying brief(s), with any reply in accordance with the Local Rules of Civil Procedure.

IV. DISCOVERY

A) Plaintiffs' Fact Sheet.

1) In every case currently part of this MDL and in all other cases that become part of this MDL by virtue of being filed in, removed to, or transferred to this Court, each Plaintiff shall complete and submit a Plaintiff Fact Sheet (“PFS”) to defense counsel.

2) Within seventy-five (75) days of the date of this Order for cases currently pending in this MDL, or within sixty (60) days of the date on which an action is filed in or transferred to and docketed in this MDL, a Plaintiff who is subject to this Order shall serve the named Defendants in that case with:

(a) A completed PFS. Plaintiffs shall sign the completed PFS and provide an executed Affidavit attesting that the information contained therein is true and correct to the best of the Plaintiff’s knowledge, information and belief, formed after due diligence and reasonable inquiry.³

A completed PFS shall be considered interrogatory answers under Fed. R. Civ. P. 33, responses to requests for production under Fed. R. Civ. P. 34, and will be governed by the standards applicable to written discovery under Federal Rules 26 through 37. The interrogatories and requests for production in the PFS shall be answered without objection.

This section does not prohibit a Plaintiff from withholding or redacting information based upon a recognized privilege. If information is withheld or redacted on the basis of privilege, Plaintiff shall provide Defendants with a privilege log. In the event that a dispute arises concerning the completeness or adequacy of a Plaintiff’s response to any request contained in the PFS, this

³ If the Plaintiff is suing in a representative or derivative capacity (e.g., on behalf of an estate, as a survivor, and/or as an assignee or subrogee), the PFS shall be completed by the person with the legal authority to represent the estate or person under legal disability.

Section shall not prohibit the Plaintiff from asserting that his or her response is adequate.

(b) Authorizations for the release of records. Plaintiffs shall provide addressed authorizations for each health care provider, including hospitals, clinics and outpatient treatment centers, and any other custodian of records identified in Plaintiff's Fact Sheet. Defendants shall provide a copy of any records received by the use of such authorization to Plaintiffs upon receipt, and Plaintiffs will reimburse the reasonable copying costs.

(i) Plaintiffs shall provide undated authorizations.

(ii) Undated authorizations constitute permission for Defendants to date (and where applicable, re-date) authorizations before sending to records custodians.

(iii) The Court encourages counsel for Plaintiffs to have their clients execute a sufficient number of undated, blank authorizations in order to assure the ability to obtain records promptly.

(c) Records in Plaintiffs' Possession. Plaintiffs shall provide the documents listed below that are currently in Plaintiffs' possession or in the possession of Plaintiffs' Counsel.

(i) Medical records in Plaintiffs' possession establishing that Plaintiff was prescribed Digitek® and the date(s) on which each prescription issued.

(ii) Pharmacy records in Plaintiffs' possession establishing that Plaintiff actually purchased and received Digitek®, including pharmacy

records of all dates on which Plaintiff filled and/or refilled a prescription for Digitek®, as well as any records of prescriptions for any other form of digoxin which was prescribed or dispensed to Plaintiff.

(iii) Medical records in Plaintiffs' possession documenting the alleged injury that Plaintiff claims to have suffered as a result of Digitek® ingestion.

3) Every Plaintiff is required to provide Defendants with a PFS that is substantially complete in all respects. "Substantially complete in all respects" requires that a Plaintiff:

(a) Answer every question in the PFS and leave no blanks, even if a Plaintiff can only answer the question in good faith by indicating "not applicable" or "I don't know";

(b) Provide the requested records authorizations; and

(c) Produce the documents requested in Section IV(A)(2)(c)(i)-(iii), or a statement certifying that there are no responsive documents.

4) Any Plaintiff who fails to comply with the PFS obligations under this Order may be subject to having his or her claims, as well as any derivative claim(s), dismissed for good cause. Good cause shall exist where (1) the Plaintiff has failed to submit a PFS, or (2) the Plaintiff has failed to substantially complete the PFS in all respects, and the PFS thus contains a material deficiency (i.e., a deficiency that prejudices Defendants through a failure to provide necessary information, thereby impeding Defendants' access to material and relevant evidence), and (3) Defendants establish to the Court that they have exhausted all efforts described in paragraph (5) below. Any

dismissal may be with or without prejudice as the Court may determine in any individual case.

5) If a Plaintiff fails to timely submit a PFS, or if Defendants receive a PFS in the allotted time but the PFS is not “substantially complete” in all respects, Defendants’ Lead Counsel shall send a deficiency letter by facsimile and U.S. mail to Plaintiffs’ Liaison Counsel and Plaintiffs’ individual representative counsel, which will allow that Plaintiff an additional thirty (30) days to serve a PFS that is “substantially complete” in all respects. The deficiency letter shall include a warning that the case is subject to dismissal under this Order if a PFS substantially complete in all respects is not received within thirty (30) days of service of the deficiency letter. This letter shall include sufficient detail for the parties to meet and confer regarding the alleged deficiencies. Should a Plaintiff fail to cure the deficiencies identified and fail to provide responses that are substantially complete in all respects (including the requested documents and signatures on all applicable authorizations) within thirty (30) days of service of the deficiency letter, Defendant may seek an Order to Show Cause why the case should not be dismissed. Any such filing shall be served on Plaintiffs’ Liaison Counsel and the Plaintiffs’ individual representative counsel, with any response to such filing to be submitted within ten (10) days following the date of service. Any such filing should include the efforts the Defendants made to meet and confer regarding the alleged deficiencies in the PFS and failure to cure.

6) In the event that an institution or medical provider to whom any authorization is presented refuses to provide records in response to that authorization, Defendants shall notify Plaintiffs’ Liaison Counsel, and the individual Plaintiff shall

execute and return within 30 days whatever form is required by that institution or provider, such as a form with an original signature, a notarized form, or the institution's own form. Should a particular form be required, Defendants will provide it to Plaintiffs' Liaison Counsel.

7) To resolve disagreements regarding the ability of Defendants to have ex parte contact with any treating physician, whether it be the result of Defendants seeking medical records of a Plaintiff that has provided a PFS or by some other means, the parties are ordered as follows:

(a) Counsel for Defendants Actavis and Defendants Mylan agree that they will not conduct ex parte communications about any particular Plaintiff with Plaintiff's treating physicians without notice to Plaintiffs' Liaison Counsel. Should the parties be unable to reach agreement about those communications, counsel for Defendants Actavis and Defendants Mylan will not conduct any such communications until the Court has resolved the issue.

(b) In connection with its regulatory obligations to investigate reports of adverse events associated with its products, Defendants Actavis and Defendants Mylan will continue its practice of requesting medical records from physicians and/or their attorneys, and may seek follow-up information from physicians by telephone or otherwise. Outside counsel for Defendants Actavis and Defendants Mylan will not initiate, prompt, participate in, or otherwise be involved with any such regulatory compliance contacts.

(c) If Counsel for Defendants Actavis and Defendants Mylan have been contacting, and continue to contact, potential consulting and testifying

medical experts, they will refrain from discussing the medical history of an individual Plaintiff if it is discovered that the individual Plaintiff is, or was, a patient of any of those experts. Counsel for Defendants will inform the expert(s) of this restriction.

B) Defendants.

1) Within thirty (30) days of the date of this Order, Defendants shall provide a corporate organization chart of all persons employed at the Little Falls Plant for the period 2005-2008, identifying job title and designation, name of department or division, and supervisors. Within seventy-five (75) days of the date of this order, Defendants will make available for Fed. R. Civ. P. 30(b)(6) depositions, corporate and/or organization representatives to address the following:

- (a) Organizational structure;
- (b) The structure of quality control and/or quality assurance and compliance; and
- (c) Organization of e-mail and electronic data.

It is anticipated that Plaintiffs will need no more than four such depositions under this subsection.

2) Within sixty (60) days of the date of this Order, Defendants shall begin to serve Plaintiffs' Steering Committee with the following documents and information to the extent that such documents are not protected from disclosure by attorney-client privilege or attorney work product:

- (a) Any and all documents concerning specifications, instructions, test methods and standard operating procedures relating to the manufacture of

Digitek® that are not included below in manufacturing records, including but not limited to instructions, testing protocols, formulations, mixing instructions, specifications for raw materials, finished goods, and particular items including moisture, heat, and pressure.

(b) Actavis shall provide any and all manufacturing records, including batch and lot records, related to all recalled Digitek® lots;

(c) Actavis shall provide any and all documentation and correspondence between Actavis and the FDA relating to all recalled Digitek® lots;

(d) Mylan shall provide any and all documentation in its possession relating to the distribution and recall of all recalled Digitek® lots;

(e) Defendants shall list the names and addresses of all insurance companies which have issued liability insurance coverage, including excess or umbrella policies, related to Digitek® claims and set forth the number or numbers of the policies involved and the amount or amounts of liability coverage provided in each policy. Defendants shall also provide a hard copy of each such policy.

3) Within ninety (90) days of the date of this Order, Defendants shall begin to serve Plaintiffs' Steering Committee with the following documents to the extent they are not protected from disclosure by attorney-client privilege or attorney work product:

(a) Any and all quality assurance/control and testing records for Digitek® and any of its component ingredients, including but not limited to records related to batch sampling, post-manufacturing testing and finished goods testing.

(b) Any and all documents related to the discovery of non-conforming Digitek® and the Defendants' response to this discovery.

4) All documents to be produced in accordance with this section shall be produced by September 1, 2009.

V. PRIVILEGED DOCUMENTS

A) Any party who withholds the production of requested documents or materials, regardless of the manner in which they are kept or maintained, on the ground of any privilege or application of the work-product doctrine must specify in writing, as to each document or thing not produced, the specific privilege(s) or doctrine(s) relied upon to withhold each document ("Privilege Log").

B) Each Privilege Log shall describe each document or thing to which a privilege or work product protection is asserted in sufficient detail to reasonably permit the party seeking discovery to assess whether or not to dispute the assertion. Details include, but are not limited to:

- 1) Custodian or source;
- 2) Date;
- 3) Author(s);
- 4) The starting and ending production number for documents produced, but redacted on the ground of privilege;
- 5) Recipient(s) (for e-mail and hard-copy communications such as letters and internal memoranda);
- 6) cc(s) (for e-mail and hard-copy communications such as letters and internal memoranda);

7) bcc(s) (for e-mail and hard-copy communications such as letters and internal memoranda);

8) Specification of the privilege claimed; and

9) A description of the document and the basis for the privilege claim.

C) The parties will produce privilege logs in Excel format or a similar electronic format that allows for text searching and organization of data.

D) A party will produce a privilege log no later than 30 days after its production of documents for which any privilege is asserted to apply, and within the same time period following any subsequent or rolling productions.

VI. DOCUMENT PRODUCTION PROTOCOL

The Parties shall reach an agreement concerning document production protocol within fourteen (14) days of the entry of this Order. This protocol will include the production format of paper and electronic documents, objective coding and metadata, privilege logs and any other applicable information. In the event the parties cannot agree, the issues will be presented to Magistrate Judge Stanley for resolution, and a hearing schedule for such issues will be set at the April Status Conference.

VII. DISCOVERY DATES AND ORDER

A) Discovery Upon Defendants

If Plaintiff intends to propound Interrogatories upon Defendants, they shall do so no later than June 1, 2009. If Plaintiff intends to propound Requests for Production of Documents upon Defendants, they shall do so no later than June 1, 2009. Plaintiff shall be limited to 50 Interrogatories, including sub-parts, but may request leave of Court for additional Interrogatories if necessary. The limits for Requests for Production and Requests to Admit shall be governed by the limits set forth in the Federal Rules of Civil Procedure.

B) Company Witness Depositions

The depositions of Defendants' company witnesses shall be concluded by December 1, 2009.

C) Liability Expert Discovery

1) Plaintiffs shall serve their reports from liability experts no later than January 1, 2010.

2) The parties shall complete their depositions of Plaintiffs' liability experts no later than March 12, 2010.

3) Defendants shall serve their reports from liability experts no later than March 31, 2010.

4) The parties shall complete their depositions of Defendants' liability experts no later than June 11, 2010.

D) Division of Cases and Trial Pool Cases

To efficiently manage discovery for all currently pending and future cases in the MDL, the cases will be divided into groups, with each group having a separate scheduling order. Within ten (10) business days of the completion of the first wave of Plaintiffs' Fact Sheets under Section IV(A)(2), the Court shall schedule a hearing for purposes of selecting the initial trial pool of cases ("Group 1"). No later than five (5) days before the hearing, Plaintiffs shall select fifteen (15) cases and the Defendants shall select fifteen (15) cases, and each side shall exchange lists of such selections and submit them to the Court outside the ECF system. Within ten (10) days after the scheduled hearing, the Court shall select a total of no more than twenty (20) of the proposed trial pool cases to constitute Group 1. The ten (10) cases not selected shall constitute the waiting list for Group 1, and shall have priority for trial selection in Group 2.

At the first hearing before the Court to select Group 1, the parties and the Court will determine a schedule to select the remaining groups, with the intent to make selections in a timely fashion and to allow enough time for discovery for each group as set forth below.

E) Discovery Initiation Date

Discovery will begin for each group pursuant to the schedule provided below. In the event that additional groups are necessary, their discovery initiation dates (“DID”) will begin thirty (30) days after the last group’s DID.

<u>Group Number</u>	<u>Discovery Initiation Date</u>
Group 1	100 days after entry of this Order
Group 2	160 days after entry of this Order
Group 3	220 days after entry of this Order
Group 4	280 days after entry of this Order
Group 5	340 days after entry of this Order
Group 6	400 days after entry of this Order

F) Scheduling Orders

Each group will have its own scheduling order based upon its DID. The orders will proceed as follows.

1) Fact Discovery

(a) No later than 90 days after the DID, the parties shall complete basic fact discovery, including but not limited to the depositions of Plaintiffs, Plaintiffs’ Digitek[®]-prescribing physicians, physicians who treated Plaintiffs for alleged digoxin toxicity, and pharmacists who filled Plaintiffs’ prescriptions for Digitek[®].

(b) After completion of the basic fact discovery outlined in paragraph 1(a), the parties will appear before the Court for a Case Management Conference.

At that time, each party will present to the Court their choice of five (5) cases that they believe to be representative plaintiffs for trial. No later than 105 days after the DID, the Court will determine which five (5) cases will be selected for trial.

(c) The parties shall complete fact discovery in the five (5) trial cases no later than 150 days after the DID.

2) Expert Discovery

(a) The five (5) trial plaintiffs shall serve their general and case-specific expert report(s) on causation and damages no later than 150 days after the DID.

(b) The parties shall complete the depositions of Plaintiffs' experts in the five (5) trial cases no later than 210 days after the DID.

(c) Defendants shall serve their general and case-specific expert report(s) on causation and damages in the five (5) trial cases no later than 240 days after the DID.

(d) The parties shall complete the depositions of Defendants' experts in the five (5) trial cases no later than 270 days after the DID.

3) Filing of Dispositive and *Daubert* Motions

(a) All dispositive motions and *Daubert* motions shall be filed and served no later than 310 days after the DID.

(b) All responses to dispositive motions and *Daubert* motions shall be filed and served no later than 340 days after the DID.

(c) All replies in support of dispositive motions and *Daubert* motions shall be filed and served no later than 370 days after the DID.

(d) A hearing will be scheduled by this Court for disposition of all dispositive and *Daubert* motions no later than 400 days after the DID.

4) Pretrial Conference

The Court will schedule a pretrial conference no later than 415 days after the DID at which time the Court will schedule the trial dates for the five (5) trial cases with the first trial to begin no later than 450 days after the DID.

G) Class Certification Discovery.

1) In addition to any other discovery sought, beginning on June 1, 2009, Defendants may serve a single set of interrogatories and a single set of requests for admission related to class certification issues on each of the named Plaintiffs listed in the Class Action Cases.

2) Beginning on June 30, 2009, Defendants may depose treating physicians of named class members and other fact witnesses with knowledge of facts relevant to class action issues.

3) Depositions of any named Plaintiffs in the Class Action Cases on class certification issues may be taken in this proceeding at any time, consistent with the need to complete such depositions before Defendants' briefing on class certification issues is due to be submitted. Discovery taken under this subparagraph shall not limit the Defendants' ability to take additional non-duplicative discovery as part of their defense of the merits of any named Plaintiff's claim.

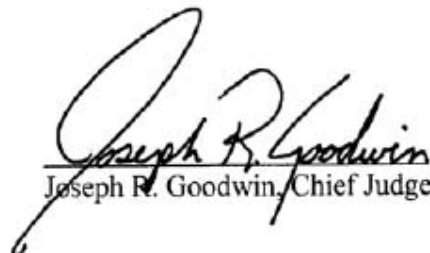
4) In addition to any other discovery sought with respect to individual cases, the proposed class representatives may serve a single set of interrogatories, production requests and requests for admissions in aid of their motion for class certification, without

prejudice to their right to seek additional discovery with leave of Court. Plaintiffs may also take depositions necessary to support their motion for class certification and limited to class certification issues. Should the parties not be able to agree on the number and scope of these depositions, they will apply to Magistrate Judge Stanley for a determination.

H) Discovery Disputes. The Court urges the parties to meet, confer and reach agreements on all disputed matters. Disputes which cannot be resolved should be brought to the Court's attention by letters, outlining the respective parties' positions. Motions, when necessary, shall be filed in accordance with the Local Rules.

The court **DIRECTS** the Clerk to file a copy of this order in 2-08-md-1968 which shall apply to each member Digitek-related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2-09-cv-0198. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsc.uscourts.gov.

ENTERED: March 5, 2009


Joseph R. Goodwin, Chief Judge